REMARKS/ARGUMENTS

In response to the Office Action mailed January 16, 2009, Applicants amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claims 1and 8 are amended, claims 13 and 14 were previously cancelled without prejudice and no new claims have been added so that Claims 1-12 currently pending. No new matter has been introduced.

Claims 1-12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending application no. 10/431,059. Claims 1-12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending application no. 11/149,466. Claims 1-12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending application no. 11/244,903.

Applicants understand that these rejections are to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However, in light of the potential amendments to the claims of the present invention and any potential amendments made to the claims of the cited applications, Applicants shall defer any arguments and/or actions until the applications actually issue.

Claims 1-12 were rejected as being unpatentable over WO 01/87372A1 to Kopia et al (Kopia) in view of U.S. Patent Publication No. 2022/0188277 to Roorda et al (Roorda) and further in view of U.S. Patent No. 4,743,327 to DeHaan et al. (DeHaan). This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In *re Vaeck*, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Kopia discloses a device and method for the treatment of restenois utilizing two drugs for release from a stent. One drug is rapamycin and the other possible choices include dexomethasone, growth factors, cytokine signal transduction inhibitors, anti-proliferative drugs as well as other agents. Kopia discloses a polymeric material for affixing the drugs. More specifically, Kopia discloses a combination of an anti-proliferative and an anti-inflammatory. The typical example of the combination is dexamethason and sirolimus.

Roorda discloses medicated stents for the treatment of vascular disease. More specifically, Rooda discloses bioactive agents for treating restenosis. Roorda discloses the use of polymeric agents for affixing the agents to the delivery device. Essentially, Roorda discloses a laundry list of different classes of drugs in anti-restenotic actions.

DeHaan discloses the use of fluropolymers.

None of the references, whether taken alone or in combination, disclose or even suggest the subject matter of independent claims 1 and 8.

In making the rejection, the Examiner states that the synergistic effect argument is not persuasive since applicants do not claim the amount of each individual ingredient and that all of the claimed elements were known in the prior art. Applicants respectfully disagree.

Claims 1 and 8 now clearly indicate that the rapamycin and 2-methoxyestradiol potentiate or have a synergistic effect each others anti-restinotic effect by downregulating both smooth muscle cell and immune cell proliferation by distinct mechanisms. In addition, the concentration range of 2-methoxyestradiol as well as rapamycin is given and has been narrowed. Specifically, about 100 micro molar 2-methoxy estradiol along with about 7 to 50 nano molar rapamycin produces a synergistic effect. In other words, the whole of the two is greater than the sum.

Secondly, Kopia never discloses or suggests the potential synergistic effects of an anti-proliferative agent (rapamycin) and an anti-angiogenic combound (panzem, 2-methoxyestradiol). The same goes for Roorda. Roorda does not disclose or suggest any concept of combination of agents. It simply discloses boiler plate language of different classes of drugs for anti-restenotic actions. Accordingly, Kopia discloses antiproliferatives and antimflammatory drugs while Roorda does not disclose any combination only a mish-mash of drugs for anti-restenotic affects.

Thirdly, as stated in *In re Rouffert* below, one cannot use the present application as a template.

> In re Rouffert, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998)
> "If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.' Sensonics, Inc. v. Aerosonic Corp. . . . (Fed. Cir. 1996)."

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be willing to interview the present case if the Examiner so desires.

A favorable Action on the merits is earnestly solicited.

Respectfully submitted,

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